December 12, 2022

Innovasis, Inc.
Michael Thomas
Regulatory Affairs Manager
614 E 3900 South
Salt Lake City, Utah 84107

Re: K223510
Trade/Device Name: Matrix HA Fusion Porous Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: November 17, 2022
Received: November 22, 2022

Dear Michael Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223510

Device Name

Matrix HA Fusion Porous Cervical IBF System

Indications for Use *(Describe)*

The Pore Matrix™ Matrix HA Fusion Porous Cervical IBF System is indicated for cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.

This device is to be used in patients who have had six weeks of non-operative treatment. The Matrix HA Fusion device is intended to be used with supplemental fixation, such as the Sapphire Medical Group Cervical Plate System. The Matrix HA Fusion device is intended to be used with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone and is to be implanted via an anterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Prepared on: 2022-12-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Innovasis Inc.
Applicant Address	614 E. 3900 South Salt Lake City UT 84107 United States
Applicant Contact Telephone	8012612236
Applicant Contact	Mr. Michael Thomas
Applicant Contact Email	mthomas@innovasis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Matrix HA Fusion Porous Cervical IBF System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical
Regulation Number	888.3080
Product Code	ODP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220875	HAcancellous™ PEEK-C Porous HA PEEK Cervical IBF System	ODP
K181115	CxHA™ PEEK Cervical IBF System	ODP

Device Description Summary

21 CFR 807.92(a)(4)

The Pore Matrix™ Matrix HA Fusion Porous Cervical IBF System is an intervertebral body fusion (IBF) device with associated instrumentation, used with bone graft material, intended to stabilize a cervical spinal segment to promote fusion which restricts motion and decreases pain. The Matrix HA Fusion Porous Cervical IBF System is implanted via an Anterior Cervical Discectomy and Fusion (ACDF) surgical approach at one level from C2-T1 and is indicated for use in skeletally mature patients with degenerative disc disease (DDD).

The Matrix HA Fusion Porous Cervical IBF Implants are made from Invibio PEEK-OPTIMA® HA Enhanced and include Pore Matrix Technology. Hydroxyapatite (HA) is fully integrated throughout the implant, including the porous layers. The Matrix HA Fusion Porous Cervical IBF Implant is made from PEEK which has a modulus of elasticity similar to human vertebral bone. The Porous Layers on the endplate contact surfaces and along the vertical walls of the graft window utilize Pore Matrix Technology, a geometry that unlike smooth PEEK, is designed to mimic anatomical cancellous bone, with interconnected spherical pores. The surface porosity is designed to promote cell signaling, on-growth, in-growth, and fusion. The Matrix HA Fusion Porous Cervical IBF Implant may provide an increased opportunity for bone ingrowth and for achieving early integration1 . In vitro performance or animal studies may not be representative of clinical performance. The Matrix HA Fusion Porous Cervical IBF Implant features a tapered nose to aid in insertion and protect the porous layer during insertion, a graft cavity to provide volume for bone graft, and is radiolucent allowing assessment of the fusion process, while three tantalum spheres enable implant visualization during the surgical procedure. The implants come in 7 heights, 6-12mm in 1mm increments, 8 Footprints with an 8° lordotic angle.

1 University of New South Wales – Surgical & Orthopaedic Research Laboratories – In-vivo evaluation of osteo integration of PEEK and surface modified PEEK in an ovine model. Note: this study was conducted on standard PEEK, not PEEK-OPTIMA® HA Enhanced from

Invibio®. The porous structure for the Matrix HA Fusion Porous Cervical IBF device has been modified from the one used for this study with the intent to increase pore interconnectivity and optimize pore size for bone in-growth.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Pore Matrix™ Matrix HA Fusion Porous Cervical IBF System is indicated for cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.

This device is to be used in patients who have had six weeks of non-operative treatment. The Matrix HA Fusion device is intended to be used with supplemental fixation, such as the Sapphire Medical Group Cervical Plate System. The Matrix HA Fusion device is intended to be used with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone and is to be implanted via an anterior approach.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are identical to the predicate device K220875.

Technological Comparison

21 CFR 807.92(a)(6)

The design, materials, manufacturing process, packaging, sterilization, sizes, and intended use are identical to the predicate. The names and part numbers and labeling format are different but substantially equivalent to the predicate.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The Pore Matrix LLC "Matrix HA Fusion Porous Cervical IBF System" is identical to the predicate device, K220875 Innovasis HAcancellous™ PEEK-C Porous HA PEEK Cervical IBF System. Pore Matrix and Innovasis developed the device jointly. The only difference is the top level part numbers. The device is manufactured using identical materials, manufacturing methods, subcontractors and sources. Therefore, the testing that was performed on the Innovasis device is fully transferable to the Pore Matrix device.